Remarks

Following entry of the above amendment, claims 9-12 are cancelled without prejudice or disclaimer in an effort to expedite prosecution. Claims 15-18 were previously cancelled. Claims 1 and 6-8 are currently amended. Following entry of the present amendment, claims 1-8 and 13-14 remain pending.

I. Obviousness-type double patenting rejection

Claims 1-12 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7,084,139 ('139). Without agreeing to the propriety of the rejection, applicants have amended claim 1 to add the characteristic XRPD peaks for the present crystalline compound.

Applicants respectfully submit that the '139 reference is directed to solvated and amorphous forms of compounds, while the presently amended claims are now directed to a specific crystalline structure of (E)-2-(5-Chlorothien-2-yl)-N-{(3S)-1-[(1S)-1-methyl-2-morpholin-4-yl-2-oxoethyl]-2-oxopyrrolidin-3-yl}ethenesulfonamide having an X-ray powder diffraction pattern comprising 2 theta angles at one or more positions selected from the group consisting of 9.1-9.2 (±0.1), 16.0-16.1 (±0.1), 18.0-18.2 (±0.1), and 18.3-18.4 (±0.1) degrees. Applicants assert that such differences between the crystalline compound of claim 1 and the solvated and amorphous compounds described in the '139 reference can translate into patentable differences in biological activity and efficacy and stability of the final pharmaceutical product.

On a related note, Applicants respectfully direct the Office's attention to numerous decisions, which are precedential, setting forth that new crystalline forms of old compounds are patentable and are not rendered obvious by old forms of the compound. See for example, *In re Cofer*, 148 USPQ 268 (CCPA 1966); *In re Irani*, 166 USPQ 24 (CCPA 1970); and *In re Grose*, 201 USPQ 57 (CCPA 1979).

Applicants assert that amended claim 1 is patentably distinct over the '129 reference by virtue of claiming a distinct and characterized crystalline form and, therefore, request withdrawal of the double patenting rejection.

II. Claim rejections under 35 U.S.C § 102

Claims 1-14 were rejected under 35 U.S.C. §102 as allegedly inherently anticipated by U.S. Patent No. 7,084,139 ('139). Applicants respectfully traverse this rejection. Applicants have

amended claims 1 and 6-8 in an effort to expedite prosecution and believe the amendments to these claims renders the Office's rejections moot. Applicants will, however, address the Office's rejections to the extent that those rejections apply to the newly amended claims in an effort to further expedite prosecution.

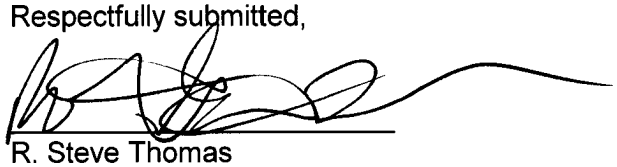
The office action stated that the '139 reference teaches using organic solvents to crystallize the material in column 24. Applicants respectfully submit that column 24 is directed to solvated forms of a compound, while the presently amended claims are directed to a specific crystalline form of (E)-2-(5-Chlorothien-2-yl)-N-{(3S)-1-[(1S)-1-methyl-2-morpholin-4-yl-2-oxoethyl]-2-oxopyrrolidin-3-yl}ethenesulfonamide.

Applicants believe it is well established that "[a]nticipation requires the presence in a single prior art reference disclosure of every element of the claimed invention." *Great Northern Corp. v. Davis Core & Pad. Co., Inc.*, 228 U.S.P.Q. 356, 358 (Fed. Cir. 1986). For example, claim 1 is limited to a specific crystalline form of (E)-2-(5-Chlorothien-2-yl)-N-{(3S)-1-[(1S)-1-methyl-2-morpholin-4-yl-2-oxoethyl]-2-oxopyrrolidin-3-yl}ethenesulfonamide having an X-ray powder diffraction pattern comprising 2 theta angles at one or more positions selected from the group consisting of 9.1-9.2 (±0.1), 16.0-16.1 (±0.1), 18.0-18.2 (±0.1), and 18.3-18.4 (±0.1) degrees. The '139 reference simply fails to teach or describe a crystalline form of the recited compound having one or more of these XRPD peaks.

Applicants assert that the differences between the crystalline compound of claim 1 and the solvated compounds described in column 24 of the '139 reference can translate into patentable differences in biological activity and efficacy and stability of the final pharmaceutical product. Applicants respectfully submit that the pending claims are patentably distinct from '139; and therefore, request favorable reconsideration of this rejection under 35 U.S.C. §102(a).

Applicants believe the present claims are in condition for allowance and such action is respectfully requested. If the Examiner has any outstanding issues with the pending claims, he is encouraged to telephone the undersigned at (919) 483-8406 for expeditious handling.

Respectfully submitted,



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